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ASIA EDITION

JHL Biotech submits clinical trial application in Europe for proposed Dornase Alfa Biosimilar

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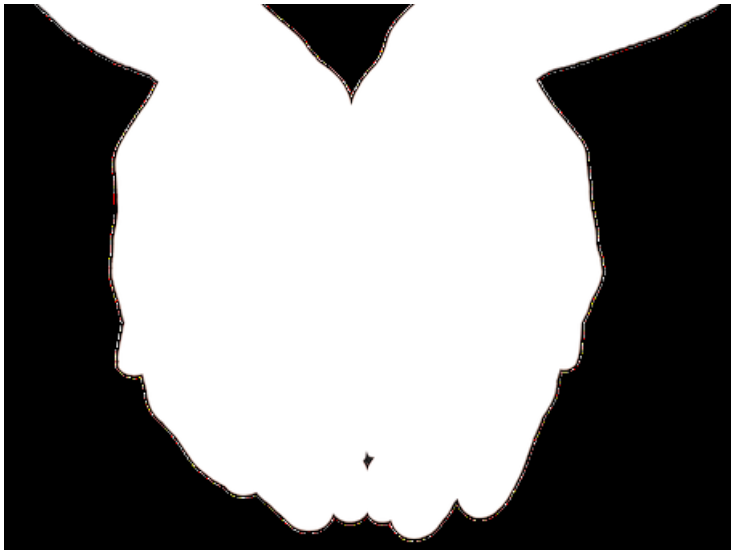
The drug, if approved, would increase affordable access to an important therapeutic for cystic fibrosis patients



Taiwan's JHL Biotech recently announced that it has submitted a Phase 1 Clinical Trial Application to the Dutch Healthcare Authority for its proposed dornase alfa biosimilar, JHL1922, to improve pulmonary function of cystic fibrosis patients.

JHL1922 would provide an affordable alternative to dornase alfa, which is indicated for daily administration to improve pulmonary function in cystic fibrosis patients in conjunction with other standard therapies.

Dornase alfa is a recombinant human deoxyribonuclease I, an enzyme which selectively cleaves deoxyribonucleic acid (DNA). JHL Biotech is developing JHL1922, a proposed similar biological product to dornase alfa which has the brand name Pulmozyme in the European Union (EU) and in the United States (US).

Dornase alfa was first approved for treatment of cystic fibrosis in the U.S. in 1993 and in Europe in 1994. The clinical trial will be conducted in the Netherlands beginning March 2018.

Cystic fibrosis affects over 100,000 people worldwide, and dornase alfa is an important part of the treatment regimen. Estimates show the cost of dornase alfa treatment is US$12,000 - $40,000 per patient per year, with only about 30,000 patients receiving this treatment.

"JHL1922 would increase affordable access to an important therapeutic for cystic fibrosis patients, and we look forward to conducting the Phase I trial in Europe," said Racho Jordanov, CEO, JHL Biotech.